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REVIEW ARTICLE

Prophylactic Mesh for Prevention of Parastomal Hernia Following End Colostomy: an Updated Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract

Objective To evaluate the efficacy of prophylactic mesh placement during end colostomy formation at reducing rates of parastomal hernia using the most recently available data.

Background Systematic reviews and meta-analyses of randomized controlled trials (RCTs) have uniformly concluded that the use of prophylactic surgical mesh when fashioning an end colostomy reduces the risk of parastomal hernia. However, recent RCTs have failed to corroborate these findings. This study was designed to provide an updated systematic review and meta-analysis evaluating the efficacy of prophylactic mesh placement during end colostomy formation.

Methods A search of Medline, EMBASE, and CENTRAL was performed. Articles were included if they were RCTs that compared the use of prophylactic mesh to no prophylactic mesh during construction of an end colostomy following colorectal resection for benign or malignant disease. The primary outcome was parastomal hernia rate. A pairwise meta-analysis was performed using inverse variance random effects.

Results From 1,089 citations, 12 RCTs with 581 patients having prophylactic mesh placement and 671 patients not having prophylactic mesh placement met inclusion criteria. Incidence of parastomal hernia was significantly reduced in patients receiving prophylactic mesh (OR 0.60, 95% CI 0.46 to 0.80, $p = 0.0003$, $I^2 = 74\%$). Results were no longer significantly different when only studies conducted in the last 5 years were analyzed ($p = 0.10$). There was no significant difference in postoperative morbidity, postoperative mortality, colostomy-specific morbidity, or length of stay between groups.

Conclusions There remains a significant reduction in the risk of parastomal hernia with the use of prophylactic mesh at the time of end colostomy formation, despite recent evidence suggesting no difference. Further contemporary trials with the application of modern surgical technology are required.

Keywords Abdominal perineal resection · Hartmann's procedure · Colorectal surgery · End colostomy · Parastomal hernia

Introduction

While contemporary surgical approaches to colorectal diseases increasingly emphasize restoration of gastrointestinal continuity with or without proximal diversion, creation of a permanent end colostomy is still required for certain pathology [1]. The most common postoperative adverse outcome following formation of an end colostomy is parastomal hernia [2]. Parastomal hernia is defined as a ventral hernia that occurs through the fascial defect created at the time of ostomy creation [3, 4]. Incidence ranges from 20 to 60% following the creation of an end colostomy [2, 5, 6]. Not only do parastomal hernias adversely impact patient quality of life (QoL), but they are also associated with life-threatening

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complications such as bowel obstruction, incarceration, and strangulation [6]. Moreover, repair of parastomal hernias is challenging, and recurrence rates generally range from 15 to 30% [2, 7].

In an attempt to avoid such morbidity, the use of prophylactic surgical mesh at the time of end colostomy formation to act as a mechanical buttress has been extensively studied. Results of previous randomized controlled trials (RCTs) have varied, but most have demonstrated a decrease in parastomal hernia rate with the use of prophylactic surgical mesh [8–10]. Subsequent systematic reviews and meta-analyses have uniformly concluded that the use of prophylactic surgical mesh significantly reduces the risk of parastomal hernia [5, 11, 12]. However, RCTs published in the past 2 years, since the most recent meta-analysis, have failed to demonstrate significantly decreased rates of parastomal hernia formation with the use of prophylactic mesh [13–15]. Therefore, it is the aim of the present study to perform an updated systematic review and meta-analysis to evaluate the efficacy of prophylactic mesh placement during end colostomy formation at reducing rates of parastomal hernia.

Methods

Search Strategy

The following databases covering the period from database inception through April 2021 were searched: Medline, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL). The search was designed and conducted by a medical research librarian with input from study investigators. Search terms included "colorectal resection," "end colostomy," "surgical mesh," "prophylactic mesh," and more (complete search strategy available in Appendix). The references of published studies and gray literature were searched manually to ensure that all relevant articles were included. This systematic review and meta-analysis are reported in accordance with the Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA).

Study Selection

Articles were eligible for inclusion if they were RCTs that compared the use of prophylactic surgical mesh to primary closure without the use of surgical mesh for patients undergoing end colostomy creation following colorectal resection in rate of postoperative parastomal hernia. Observational studies were not eligible for inclusion. Relevant single-arm studies were excluded. Studies including less than 10 patients, patients undergoing emergent operation, or patients undergoing intervention for non-colorectal disease (e.g., peritoneal metastases) were excluded. Studies were not discriminated on the basis of language. Lastly, opinions, case reports, systematic reviews, meta-analyses, letters to editors, and editorials were excluded.

Outcomes Assessed

The primary outcome was parastomal hernia rate. Parastomal hernia was defined on the basis of clinical and/or radiographic findings. Clinically, parastomal hernias were most commonly defined by any detectable bulge adjacent to a colostomy [9, 14, 16]. Two studies used the European Hernia Society Parastomal Hernia Classification to clinically define parastomal hernias, which is based on intraoperative measurements of hernia orifice size [4, 17, 18]. Radiographically, parastomal hernias were most commonly defined by the Moreno-Matias classification [3, 8, 10, 13, 18, 19]. The classification grades parastomal hernias from 0 to III; Type 0, no visible hernia sac; Type Ia, hernia sac less than 5 cm adjacent to the loop of bowel forming the colostomy without other contents; Type Ib, hernia sac greater than 5 cm adjacent to the loop of bowel forming the colostomy without other contents; Type II, hernia sac adjacent to the loop of bowel forming the colostomy with omental contents; and Type III, hernia sac adjacent to the loop of bowel forming the colostomy with a separate loop of bowel [3].

Secondary outcomes included (1) operative time in minutes, (2) postoperative LOS in days, (3) rate of reoperation, (4) 30-day overall postoperative morbidity, (5) 30-day overall postoperative mortality, (6) incidence of SSI, and (7) incidence of colostomy specific 30-day complications (e.g., colostomy necrosis, colostomy stenosis). LOS was defined as the time from the end of the index procedure to the time the patient left the hospital following their index procedure in all included studies. Postoperative morbidity was defined as any documented deviation from the expected postoperative course documented in patient medical records or database records. SSIs were defined according to the Centre for Disease Control and Prevention [20]. Colostomy necrosis was defined as arterial insufficiency resulting in lack of adequate blood supply to the stoma to sustain tissue integrity [21]. Colostomy stenosis was defined as luminal narrowing at or above the level of the anterior abdominal wall fascia [21].

Data Extraction

Two reviewers independently evaluated the systematically searched titles and abstracts using a standardized, pilot-tested form. Discrepancies that occurred at the title and abstract screening phases were resolved by inclusion of the study. At the full-text screening stage, discrepancies were resolved by consensus between the two reviewers. If the disagreement persisted, a third reviewer was consulted.

Two reviewers independently conducted data extraction into a data collection form designed a priori. The extracted data included study characteristics (e.g., author, year of publication, study design), patient demographics (e.g., age, gender, body mass index (BMI), comorbidities), treatment characteristics (e.g., operative approach, index operation, type of mesh, mesh location, operative time), postoperative morbidity (e.g., parastomal hernia, colostomy specific complications, surgical site infection (SSI), reoperation), and length of stay (LOS).

Risk of Bias Assessment

Risk of bias for each included study was assessed using the Cochrane Risk of Bias Tool for Randomized Controlled Trials 2.0 [22]. The Cochrane Risk of Bias Tool analyzes RCTs according to randomization process, assignment to intervention, adherence to intervention, missing outcome data, outcome measurement, and outcome reporting. Studies were assigned low risk of bias, some concerns for bias, and high risk of bias in each of the aforementioned domains, as well as overall. Two reviewers assessed the quality of the studies independently. Discrepancies were discussed amongst the reviewers until consensus was reached.

Statistical Analysis

All statistical analyses and meta-analyses were performed on STATA version 14 (StataCorp, College, TX) and Cochrane Review Manager 5.3 (London, UK). The threshold for statistical significance was set a priori at a p of < 0.05. A pairwise meta-analysis was performed using an inverse variance, random effects model for all meta-analyzed outcomes. Pooled effect estimates were obtained by calculating the mean difference (MD) in outcomes for continuous variables and risk ratios (RR) for dichotomous variables along with their respective 95% confidence intervals (CI) to confirm the effect size estimation. In addition, mean and standard deviation (SD) was estimated for studies that only reported median and interquartile range using the method described by Wan et al. [23]. For studies that did not report standard deviation or interquartile range, we contacted the authors for missing data. Data was presumed to be unreported if no response was received from study authors within 2 weeks from the index point of contact. A funnel plot for assessing publication bias was not used as this review contained less than 10 studies. Assessment of heterogeneity was completed using the inconsistency (I^2) statistic. An I^2 greater than 50% was considered to represent considerable heterogeneity [24]. Bias in meta-analyzed outcomes was assessed with funnel plots when data from more than 10 studies were included in the analysis [25]. A leave-one-out sensitivity analysis was performed by iteratively removing one study at a time from the inverse variance, random effects model to ensure that pooled effect estimates were not driven by a single study. Additionally, a sensitivity analysis on the basis of study publication date and high risk of bias according to the Cochrane Risk of Bias Tool for Randomized Controlled Trials 2.0 was performed to ensure that pooled effect estimates were not impacted by low quality, potentially biased data. Lastly, sensitivity analyses based on year of publication (i.e., excluding studies published more than 5 years prior), mesh location, and operative approach were performed. For outcomes that were reported in less than three studies, a systematic narrative summary was provided [26].

Results

Study Characteristics

From 1,511 citations, 12 RCTs met inclusion criteria [8–10, 13–19, 27, 28]. A PRISMA flow diagram of the study selection process is illustrated in Fig. 1. Included studies were conducted between 2008 and 2021. In total, 581 patients (37.3% female, mean age: 66.7 years, mean BMI: 26.1 kg/m^2) underwent colostomy formation with prophylactic mesh, and 671 patients (48.5% female, mean age: 66.2 years, mean BMI: 27.3 kg/m^2) did not have prophylactic mesh placed. The majority of operations were abdominal perineal resections in both groups (mesh: 82.2%; no mesh: 76.5%). The most common indication for operation was colorectal malignancy (mesh: 86.9%; no mesh: 85.2%). Six studies included exclusively patients undergoing open operations [10, 13, 16, 18, 19, 28], three studies included exclusively patients undergoing laparoscopic operations [8, 9, 17], and the remaining three studies evaluated both open and laparoscopic procedures [14, 15, 27]. There was no significant difference in operative time between the two groups (SMD 0.39, 95% CI − 0.37 to 1.16, $p = 0.31$, $I^2 = 96\%$). Detailed study characteristics of the included studies are reported in Table 1.

Mesh Details

The specific mesh utilized in the included studies was variable (Table 2). The majority of meshes used were a lightweight polypropylene material. Three of the included studies placed the mesh intraperitoneally, nine studies placed the mesh in the retromuscular space, and one study placed the mesh in the preperitoneal space. All stomas were placed through the rectus abdominis, and seven of the included studies utilized preoperative stoma therapist marking. Two studies solely reported clinically detectable parastomal hernias [16, 28], four studies solely reported radiological detectable parastomal hernias [8–10, 13], and the remaining six

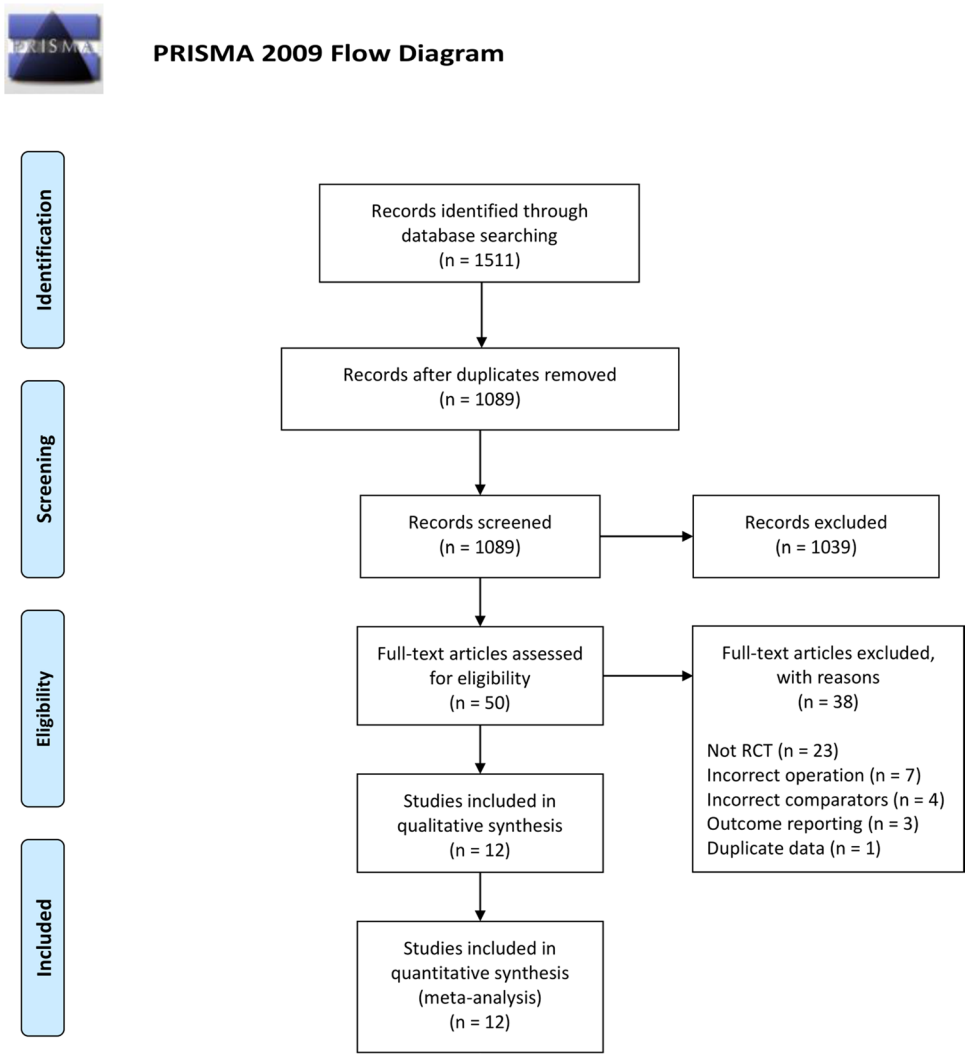


Fig. 1 PRISMA diagram—transparent reporting of systematic reviews and meta-analysis flow diagram outlining the search strategy results from initial search to included studies

studies defined parastomal hernias according to both clinical and radiological classifications [14, 15, 17–19, 27].

Parastomal Hernia

Incidence of postoperative parastomal hernia was reported by all included studies. Overall, 137 patients (24.0%) in the prophylactic mesh group and 243 patients (37.6%) in the no prophylactic mesh group developed parastomal hernias. Pooling of data demonstrated a significant reduction in the risk of developing a parastomal hernia in patients receiving prophylactic mesh placement (OR 0.60, 95% CI 0.46 to 0.80, $p=0.0003$, $I^2=74\%$) (Fig. 2). A funnel plot analysis suggested slight asymmetry suggestive of heterogeneity (Fig. 3). Significantly decreased rates of parastomal hernia were also observed on sensitivity analyses on the basis of risk of bias, surgical approach, and mesh location. Results were no longer significantly different when only studies conducted in the last 5 years were analyzed (Mesh $n=361$, No Mesh $n=440$, OR 0.76, 95% CI 0.55 to 1.05, $p=0.10$, $I^2=71\%$).

Postoperative Morbidity

Eleven studies compared patients undergoing end colostomy formation with and without prophylactic mesh in terms of 30-day overall postoperative morbidity. There was no difference between groups (OR 0.78, 95% CI 0.47 to 1.32, $p=0.36$, $I^2=71\%$) (Fig. 4). Results were unchanged on sensitivity analyses.

Nine studies evaluated 30-day overall postoperative mortality. There was no difference between groups (OR 1.38, 95% CI 0.69–2.73, $p=0.36$, $I^2=4\%$). Results were unchanged on sensitivity analyses.

Colostomy-specific morbidity was unchanged with the use of prophylactic mesh. Rates of colostomy necrosis (OR 0.85, 95% CI 0.39 to 1.89, $p=0.69$, $I^2=0\%$) and colostomy stenosis (OR 2.69, 95% CI 0.63 to 4.55, $p=0.30$, $I^2=0\%$)

Table 1 Study characteristics of included randomized controlled trials (*N* number of patients, *SD* standard deviation, *kg* kilograms, *m* meters, *OR* operation, *CRC* colorectal cancer, *NR* not reported)

Study	Arm	*N*	Mean age, years (SD)	*N* Female (%)	Mean BMI, kg/m^2 (SD)	Index OR (%)	Indication for index OR (%)	Surgical approach (%)	Comorbidities (%)
Jänes (2009)	Mesh	27	70	12 (44.4)	26	-	CRC (92.6), diverticulitis (3.7), IBD (3.7)	Laparotomy (100)	-
	No Mesh	27	71	11 (40.7)	27	-	CRC (81.4), diverticulitis (11.1), IBD (3.7), other (3.7)	Laparotomy (100)	-
Serra-Aracil (2009)	Mesh	27	67.5 (8.8)	5 (18.5)	25.6 (2.9)	APR (100)	CRC (100)	Laparotomy (100)	-
	No Mesh	27	67.2 (9.7)	8 (29.6)	27.3 (3.5)	APR (100)	CRC (100)	Laparotomy (100)	-
Lopez-Cano (2012)	Mesh	19	72.2 (7.6)	8 (42.1)	26.3 (3.2)	APR (100)	CRC (100)	Laparoscopy (100)	Previous hernia (15.8), diabetes (84.2), COPD (31.6), prostatism (42.1), constipation (15.8)
	No Mesh	17	65.9 (13.9)	10 (58.8)	27.5 (4.7)	APR (100)	CRC (100)	Laparoscopy (100)	Previous hernia (11.8), diabetes (76.5), COPD (23.5), prostatism (29.4), constipation (35.3)
Tarcoveanu (2014)	Mesh	20	-	-	-	APR (100)	CRC (100)	Laparotomy (100)	Diabetes (10)
	No Mesh	22	-	-	-	APR (100)	CRC (100)	Laparotomy (100)	Diabetes (9.1)
Fleshman (2014)	Mesh	55	60.2 (13.6)	25 (45.5)	26.2 (4.6)	APR (44.0), proctocolectomy (18.2), colostomy (14.6), ileostomy (5.5), LAR (7.3), sigmoid resection (5.5), stoma relocation (9.1), laparoscopic (36.4)	CRC (40.0), Crohn's (16.4), UC (16.4), fecal incontinence (12.8), anal cancer (5.5), constipation (7.3), IBS (5.5), rectal prolapse (1.8)	Laparotomy (63.6), Laparoscopy (36.4)	-
	No Mesh	58	59.1 (14.4)	29 (50.0)	34.7 (4.1)	APR (41.4), proctocolectomy (19.0), colostomy (12.1), ileostomy (12.1), LAR (5.2), sigmoid resection (3.5), stoma relocation (6.1), laparoscopic (31.0)	CRC (43.1), Crohn's (19.0), UC (15.5), fecal incontinence (6.9), anal cancer (5.2), constipation (3.5), IBS (3.5), congenital GI abnormality (1.8), radiation proctitis (1.8)	Laparotomy (69.0), Laparoscopy (31.0)	-

Table 1 (continued)

Study	Arm	*N*	Mean age, years (SD)	*N* Female (%)	Mean BMI, kg/m^2 (SD)	Index OR (%)	Indication for index OR (%)	Surgical approach (%)	Comorbidities (%)
Lambrecht (2015)	Mesh	32	64 (4.0)	5 (15.6)	24.6 (0.6)	APR (62.5), pelvic exenteration (9.4), Hartmann's (28.1)	CRC (100)	Laparotomy (100)	Previous hernia (6.3), COPD (9.4), cardiac disease (37.5)
	No Mesh	26	63 (4.1)	10 (38.5)	25.5 (0.8)	APR (100)	CRC (100)	Laparotomy (100)	Previous hernia (11.5), COPD (7.7), cardiac disease (34.6)
Vierimaa (2015)	Mesh	35	67.1 (10.7)	17 (48.6)	26.2 (4.6)	APR (100)	CRC (100)	Laparoscopy (100)	-
	No Mesh	35	65.1 (11.7)	16 (45.7)	25.4 (4.3)	APR (100)	CRC (100)	Laparoscopy (100)	-
Lopez-Cano (2016)	Mesh	24	70.5 (9.5)	3 (12.5)	25.3 (2.8)	APR (100)	CRC (100)	Laparoscopy (100)	Previous hernia (16.7), diabetes (33.3), COPD (37.5). prostatism (37.5), constipation (4.3)
	No Mesh	28	67.3 (13.6)	8 (28.6)	26.9 (4.4)	APR (100)	CRC (100)	Laparoscopy (100)	Previous hernia (10.7), diabetes (21.4), COPD (49.9). prostatism (35.7)
Brandsma (2017)	Mesh	67	64.1	29 (37.2)	26.5	APR (majority)	CRC (87.5), fecal incontinence (5.6), IBD (2.8), other (4.2)	Laparotomy (100)	Previous hernia (16.7), diabetes (8.3), AAA (1.4), immunosuppression (2.8)
	No Mesh	66	63.6	29 (40.3)	26.7	APR (majority)	CRC (88.5), fecal incontinence (5.1), IBD (1.3), other (2.6)	Laparotomy (100)	Previous hernia (17.9), diabetes (9.0), AAA (7.7), immunosuppression (1.3)
Odensten (2019)	Mesh	114	69.7	40 (35.1)	26.1	-	CRC (93.0), benign disease (7.0)	Laparotomy (100)	-
	No Mesh	118	69.9	56 (47.5)	26.3	-	CRC (89.8), benign disease (10.2)	Laparotomy (100)	-
Prudhomme (2021)	Mesh	98	67.2 (12.4)	41 (41.8)	25.6 (4.6)	-	CRC (83.7), fecal incontinence (22.4), IBD (3.1), pelvic reoperation (7.1)	Laparotomy, Laparoscopy	COPD (7.1)
	No Mesh	101	70.5 (11.1)	44 (43.6)	24.8 (4.7)	-	CRC (89.1), fecal incontinence (21.8), pelvic reoperation (8.9)	Laparotomy, Laparoscopy	COPD (5.0)

Table 1 (continued)

Study	Arm	*N*	Mean age, years (SD)	*N* Female (%)	Mean BMI, kg/m^2 (SD)	Index OR (%)	Indication for index OR (%)	Surgical approach (%)	Comorbidities (%)
Correa-Martinez (2021)	Mesh	63	65.0[a]	21 (33.3)	27.6[a]	Colostomy only (10), Hartmann's (19), APR (71)	CRC (85.7), benign disease (14.3)	Laparotomy (67.7), Laparoscopy (33.3)	Diabetes (9.5), cardiac disease (14.3), previous abdominal surgery (38.1), previous stoma (13.9)
	No Mesh	146	63.6[a]	66 (45.8)	28.2[a]	Colostomy only (18.5), Hartmann's (19.2), APR (54.8), NR (7.5)	CRC (79.5), benign disease (16.4), NR (4.1)	Laparotomy (53.4), Laparoscopy (41.8), NR (4.8)	Diabetes (13.0), COPD (9.5), cardiac disease (6.8), previous abdominal surgery (50.7), previous stoma (8.9)

[a]Estimated based on Wan et al.(2014) method

were not significantly different between groups (Fig. 5). The incidence of superficial surgical site infection SSI (sSSI) at the colostomy or a separate surgical site was not significantly different between the prophylactic mesh and the no prophylactic mesh group (OR 0.94, 95% CI 0.52 to 1.67, $p = 0.82$, $I^2 = 0\%$).

Differences in postoperative LOS between patients with and without prophylactic mesh placement were reported by four studies. Pooled analysis with SMD did not result in a difference in LOS between the two groups (SMD − 0.18, 95% CI − 0.64 to 0.28, $p = 0.45$, $I^2 = 85\%$).

Risk of Bias

Figure 6 presents the risk of bias analysis according to the Revised Cochrane Risk-of-Bias Tool for included RCTs. Seven studies were at an overall low risk of bias, while two were at high risk of bias. Aside from Tarcoveanu et al., included studies were uniformly at a low risk of bias according to lack of missing data, outcome reporting, and randomization scheduling [28]. Tarcoveanu et al. was one of two studies found to be at high risk of bias; outcome reporting was incomplete in their publication, and there was a lack of details with regard to their randomization process [28]. Three studies were found to have an overall unclear risk of bias. Lambrecht et al. excluded two patients following their randomization to the control group (no mesh) and did not use an intention to treat analysis [19]. Lopez-Cano et al. conducted an RCT in 2016 whereby their statistical analysis was performed on a per-protocol basis as opposed to an intention-to-treat [8]. In an RCT from 2015, it was unclear whether Vierimaa et al. blinded outcome assessors [17].

Discussion

This updated systematic review and meta-analysis of RCTs evaluating the use of prophylactic mesh during formation of end colostomies demonstrated similar results to previous reviews [11, 12]. The risk of parastomal hernia formation was significantly reduced with the use of prophylactic mesh; however, significance was not observed in a subgroup analysis only including studies published over the past 5 years. Other postoperative outcomes, including 30-day postoperative morbidity, 30-day postoperative mortality, incidence of colostomy necrosis, incidence of colostomy stenosis, incidence of sSSI, and LOS, were not different between patients receiving and not receiving prophylactic mesh. Overall risk of bias according to the Revised Cochrane Risk-of-Bias Tool was low for seven studies, unclear for three studies, and high for two studies.

The use of prophylactic non-absorbable synthetic mesh when creating an end colostomy was strongly

Table 2 Prophylactic mesh characteristics reported in the included randomized controlled trials (*N*, number of patients)

Study	*N*	Type of mesh	Location of mesh	Location of stoma	Definition of parastomal hernia
Jänes (2009)	27	Vypro (Ethicon)—***synthetic***	Retromuscular	Transrectus	Clinical: any protrusion in the vicinity of the stoma
Serra-Aracil (2009)	27	Ultrapro (Ethicon)—***synthetic***	Retromuscular	Transrectus; marked by stoma nurse	Radiologic: Moreno-Matias et al. (2009) scale 1b—III
Lopez-Cano (2012)	19	PROCEED (Ethicon)—***synthetic***	Retromuscular	Transrectus; marked by stoma nurse	Radiologic: a loop of intestine or any abdominal organ, as well as preperitoneal fat, protruding through the defect alongside the ostomy
Tarcoveanu (2014)	20	Polypropylene—***synthetic***	Preperitoneal	Transrectus	Devlin classification (1983)
Fleshman (2014)	55	Strattice (Allergan)—***biologic***	Retromuscular	Transrectus; marked by stoma nurse	Clinical and radiologic
Lambrecht (2015)	32	Prolite Ultra (Atrium), Parietene Light (Covidien)—***synthetic***	Retromuscular	Transrectus	Clinical: a bulge associated with the stoma Radiologic: according to Moreno-Matias et al. (2009)
Vierimaa (2015)	35	DynaMesh-IPOM (FEG Textiltechnik)—***synthetic***	Intraperitoneal	Transrectus	European Hernia Society Parastomal Hernia Classification (2014)
Lopez-Cano (2016)	24	Physiomesh (Ethicon)—***synthetic***	Intraperitoneal	Transrectus; marked by stoma nurse	Radiologic: Moreno-Matias et al. (2009) scale 1b—III
Brandsma (2017)	133	Parietene Light (Covidien)—***synthetic***	Retromuscular	Transrectus; marked by stoma nurse	European Hernia Society Parastomal Hernia Classification (2014), Moreno-Matias et al. (2009)
Odensten (2019)	114	Lightweight polypropylene—***synthetic***	Retromuscular	Transrectus; marked by stoma nurse	Radiologic: Moreno-Matias et al. (2009) scale Ia—III
Prudhomme (2021)	98	Lightweight polypropylene (e.g., Parietex, Sofradim)—***synthetic***	Retromuscular	Transrectus; marked by stoma nurse	Clinical: any detectable bulge in the vicinity of the colostomy with the patient erect or supine or during a Valsalva maneuver Radiologic: any intra-peritoneal structure or organ outside the parietal peritoneum
Correa-Marinez (2021)	63	Ultrapro (Ethicon)—***synthetic***	Retromuscular	Transrectus	Clinical and radiologic: any herniation of intraabdominal content beyond the abdominal wall or a hernia sac identified in the prone or supine position

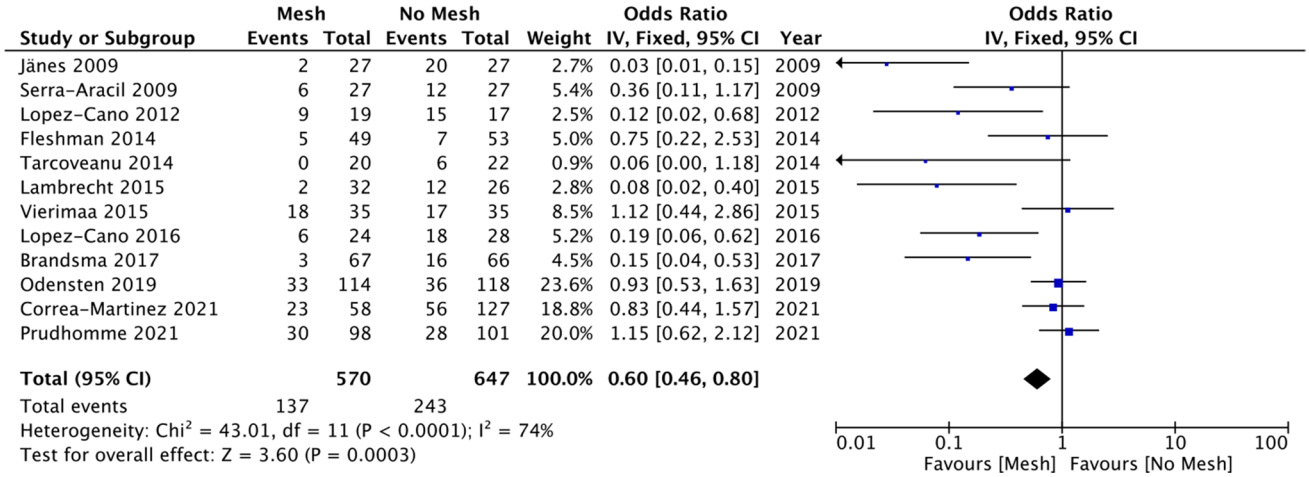


Fig. 2 Incidence of parastomal hernia—random effect meta-analysis comparing patients receiving and not receiving prophylactic surgical mesh

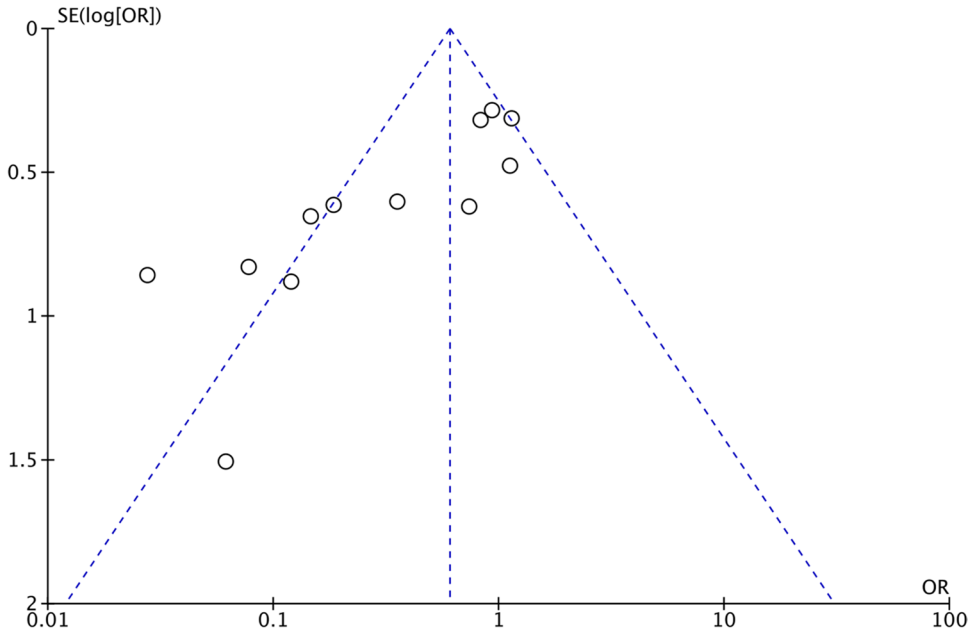


Fig. 3 Incidence of parastomal hernia—funnel plot for parastomal hernia incidence random effect meta-analysis

recommended in the 2018 European Hernia Society Parastomal Hernia Guidelines [29]. This was on the basis of a low risk of adverse events with the use of mesh, the low relative cost of synthetic mesh, and the consistency of reported outcomes in RCTs evaluating their use. Recently, however, large RCTs have published data inconsistent with parastomal hernia outcomes reported in earlier trials. In 2019, Odensten et al. presented data from their STOMA-MESH trial which failed to demonstrate a reduction in both clinical and radiological incidence of parastomal hernia following end colostomy formation via laparotomy with the use of prophylactic mesh [13]. Similarly, Prudhomme et al. in 2020 found no significant difference between the mesh and the no mesh groups, in patients undergoing both laparoscopic and open end colostomy formation [14]. Most recently, results from the Stoma-Const trial in Sweden, which compared three techniques for end colostomy formation (cruciate incision with no mesh vs. circular incision with no mesh vs. mesh) found no difference in incidence of parastomal hernia at 12 months postoperatively between the three techniques [15]. Ultimately, pooled analysis with previously published data failed to alter the significant reduction in parastomal hernia formation, which the 2018 European Hernia Society guidelines are predicated on. Nonetheless, these findings should prompt future RCTs aimed at addressing this clinical equipoise, especially in the setting of evolving approaches to colorectal pathology such as minimally invasive surgery,

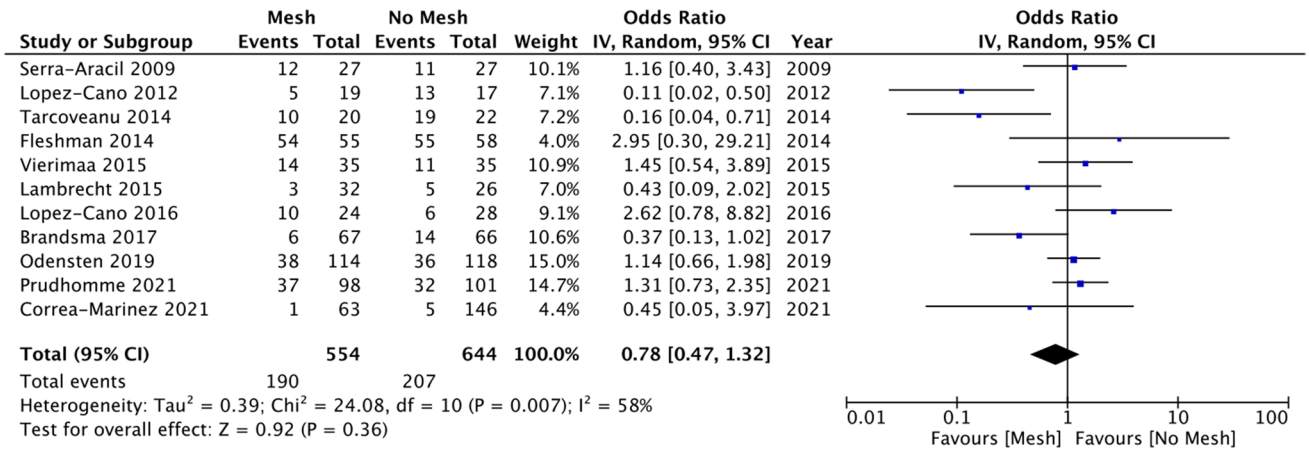
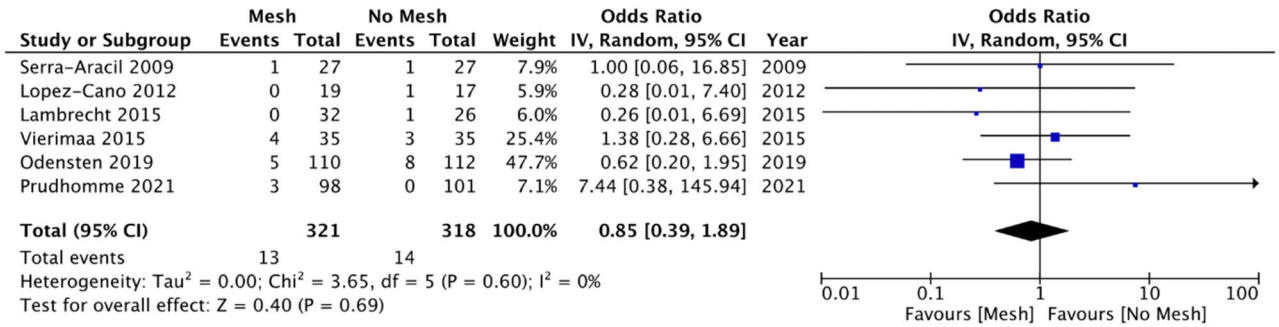


Fig. 4 Overall postoperative morbidity—random effect meta-analysis comparing patients receiving and not receiving prophylactic surgical mesh

A



B

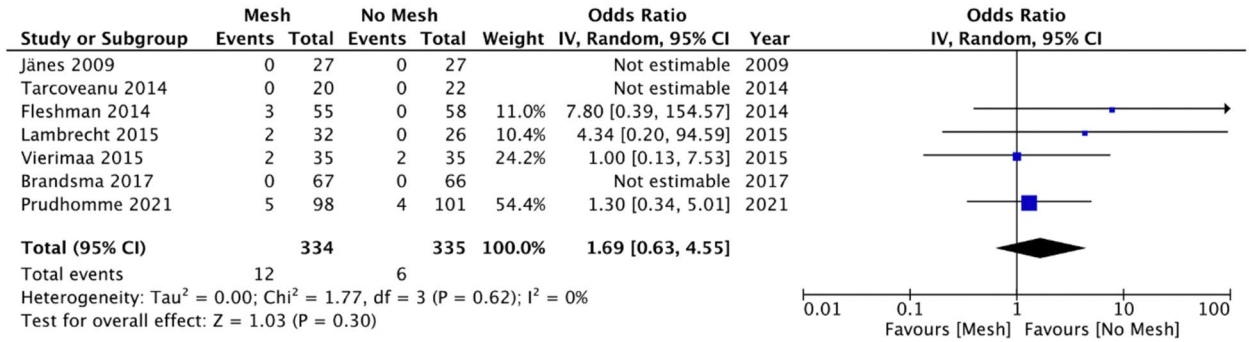


Fig. 5 Postoperative colostomy-specific morbidity (**A** colostomy necrosis, **B** colostomy stenosis)—random effect meta-analysis comparing patients receiving and not receiving prophylactic surgical mesh

perioperative optimization, and enhanced recovery after surgery pathways [30–32]. Moreover, future RCTs should be large and adequately powered to assess incidence of parastomal hernias as the primary outcome. According to the findings of the present study, and assuming a power of 80% and $p < 0.05$ as significant, 170 patients would be required in each arm to adequately assess this clinical question.

The colorectal patient population has similarly evolved. Today, patients are larger, more comorbid, and subjected to a greater variety of neoadjuvant treatments, all of which may contribute to poor tissue healing and increased propensity

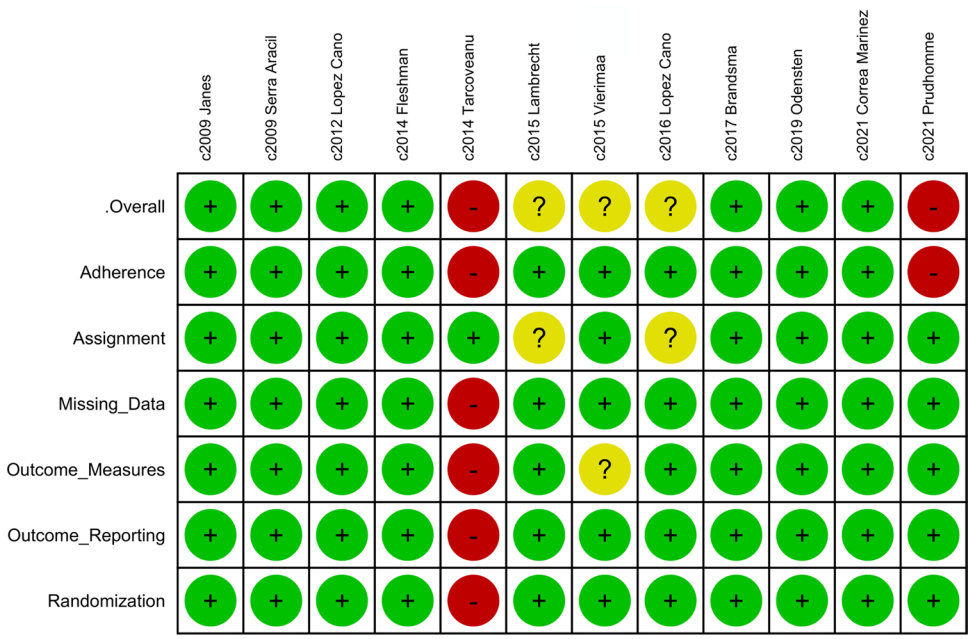


Fig. 6 Cochrane Risk of Bias Tool for Randomized Controlled Trials 2.0 individual study analyses

for hernia formation [33–35]. The obesity epidemic in particular, and its association with increased risk of developing colorectal cancer, has increased intraoperative difficulty and worsened postoperative clinical outcomes in colorectal surgery [36, 37]. Obesity significantly increases the risk of parastomal hernia development. A waist circumference of greater than 100 cm is associated with a 75% risk of developing parastomal hernia [38]. In one of the included studies, Lopez-Cano et al. found that a subcutaneous fat thickness of greater than 23 mm was associated with an 80% risk of parastomal hernia formation [9]. Altogether, these patients may benefit disproportionately from prophylactic surgical mesh placement at the time of end colostomy formation. Further study focused specifically on the obese colorectal patient is warranted.

In keeping with previous reviews, the majority of included studies (91.7%) evaluated the use of synthetic non-absorbable mesh [11, 12]. Similarly, prophylactic mesh placed in the sublay position was most common in both the present review as well as previous reviews. While there are no data to suggest differences between biologic and synthetic mesh placement, nor between sublay and intraperitoneal mesh placement, the results of this study are more applicable to synthetic, sublay prophylactic mesh placement [39, 40]. Studies comparing different types of mesh and different mesh positioning for parastomal hernias specifically would be a valuable addition to the literature.

The strengths of this systematic review and meta-analysis include the comprehensive systematic literature search, quality of the included evidence, analysis of prospective randomized controlled data, and the inclusion of updated data compared to previous systematic reviews and meta-analyses. Specifically, the present review includes three large RCTs not published at the time of the most recent systematic reviews and meta-analyses [11, 12]. The limitations of the present study include heterogeneity amongst the included studies, variability in surgical technique (i.e., open, laparoscopic, specific operation, mesh positioning) and type of surgical mesh, and lack of reporting of secondary outcomes precluding robust analyses of specific postoperative complications and colostomy-specific morbidity. The I^2 was greater than 70% for the primary outcome as well as multiple secondary outcomes [41]. Moreover, while the majority of included studies evaluated polypropylene mesh in the sublay position, the specific brand of mesh varied significantly. Three studies also assessed intraperitoneal mesh placement as opposed to sublay positioning [8, 9, 17]. Regardless, the patient populations amongst included studies were strikingly similar, and thus the results of the present review can be applied safely to overweight and obese patients undergoing laparoscopic or open abdominal perineal resection for colorectal cancer.

Despite recent RCTs suggesting a lack of benefit with the use of prophylactic surgical mesh during the formation of end colostomies, this updated systematic review and meta-analysis of RCTs found a similar reduction in the risk of parastomal hernia with the use of prophylactic mesh as compared to previous reviews. A subgroup analysis of studies published over the past 5 years, however, failed to demonstrate the same benefit. Further large-scale RCTs are required to elucidate whether prophylactic surgical mesh in the setting of contemporary approaches to colorectal pathology and end colostomy formation is beneficial [42].

Appendix. PRISMA 2020 checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge	4,5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses	5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses	5,6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted	5
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used	5
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process	5–7
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process	7

Section and Topic	Item #	Checklist item	Location where item is reported
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect	6,7
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information	6,7
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process	8
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results	8,9
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5))	8,9
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions	8,9
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses	8
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used	8,9
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression)	8,9
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results	9

Section and Topic	Item #	Checklist item	Location where item is reported
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases)	9
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome	NA
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram	9,10
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded	9
Study characteristics	17	Cite each included study and present its characteristics	9
Risk of bias in studies	18	Present assessments of risk of bias for each included study	12
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots	10
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies	12
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect	9–12
	20c	Present results of all investigations of possible causes of heterogeneity among study results	10
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results	9–12
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed	12
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed	NA
DISCUSSION			

Section and Topic	Item #	Checklist item	Location where item is reported
Discussion	23a	Provide a general interpretation of the results in the context of other evidence	12,13
	23b	Discuss any limitations of the evidence included in the review	15
	23c	Discuss any limitations of the review processes used	15
	23d	Discuss implications of the results for practice, policy, and future research	14,15
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered	NA
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared	NA
	24c	Describe and explain any amendments to information provided at registration or in the protocol	NA
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review	3
Competing interests	26	Declare any competing interests of review authors	2
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review	NA

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Author Contribution Conception and design of the study—all authors.
Acquisition of data—McKechnie, Lee.
Analysis and interpretation of data—all authors.
Drafting and revision of the manuscript—all authors.
Approval of the final version of the manuscript—all authors.
Agreement to be accountable for all aspects of the work—all authors.

Declarations

Conflict of Interest The authors declare no competing interests.

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